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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte IFTIKHAR KHAN and NAZIR KHAN

Appeal 2010-003194
Application 10/812,380
Technology Center 3700

Before WILLIAM F. PATE III, STEVEN D.A. McCARTHY and
MICHAEL W. O'NEILL, *Administrative Patent Judges*.

McCARTHY, *Administrative Patent Judge*.

DECISION ON APPEAL¹

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

1 The Appellants appeal under 35 U.S.C. § 134 from the Examiner's
2 decision finally rejecting claims 1-5, 7-10, 12-14, 17 and 18 under 35 U.S.C.
3 § 103(a) as being unpatentable over Squitieri (US 6,102,884, issued Aug. 15,
4 2000) and Parks (US 5,399,173, issued Mar. 21, 1995); finally rejecting
5 claims 6, 11, 15, 16, 19 and 20 under § 103(a) as being unpatentable over
6 Squitieri, Parks and Trerotola (US 5,591,226, issued Jan. 7, 1997); finally
7 rejecting claim 10 under § 103(a) as being unpatentable over Squitieri and
8 Trerotola; and finally rejecting claim 17 under § 103(a) as being
9 unpatentable over Squitieri, Parks and Twardowski (US 5,509,897, issued
10 Apr. 23, 1996).² An oral hearing was held on July 22, 2010. We have
11 jurisdiction under 35 U.S.C. § 6(b).

12 We sustain the rejection of claim 17, which is illustrative of the
13 claimed subject matter:

- 14 17. A method for performing hemodialysis on a
15 patient comprising:
- 16 a. surgically inserting an arteriovenous shunt
17 into a patient, wherein said arteriovenous
18 shunt comprises:
- 19 i. an arterial graft comprising a body, a lead
20 end and a terminal end, said lead end being
21 configured for subcutaneous connection to
22 an artery by anastomosis, wherein said
23 arterial graft has a first diameter; and
24

² The Examiner also has entered an objection to the drawing. Final Office Action mailed June 16, 2008 at 2. An objection to the drawings is subject to review by petition and is not appealable to the Board of Patent Appeals and Interferences. *See Ex Parte Frye*, 94 U.S.P.Q.2d 1072, 1077-78 (BPAI 2010).

- 1 ii. a single lumen venous outflow catheter
2 comprising an intake end and a depositing
3 end, said depositing end being configured
4 for insertion through a vein into the right
5 atrium of the heart, wherein said venous
6 outflow catheter has a second diameter
7 different from said first diameter; and
- 8 iii. a cylindrical cuff operable to direct passage
9 of blood from said arterial graft to said
10 venous outflow catheter, said cuff
11 comprising an inlet in blood communication
12 with an outlet:
 - 13 1. said inlet being disposed about and
14 connected to said terminal end of said
15 arterial graft; and
 - 16 ii. said outlet being disposed about and
17 connected to said intake end of said venous
18 outflow catheter; wherein said cuff provides
19 a secure fit for said arterial graft first
20 diameter and said venous outflow catheter
21 second diameter.
 - 22 b. connecting said arterial graft to a
23 hemodialysis apparatus;
 - 24 c. collecting blood from the patient through
25 said arterial graft;
 - 26 d. passing said blood through the hemodialysis
27 apparatus;
 - 28 e. collecting purified blood from hemodialysis
29 apparatus; and
 - 30 f. transmitting said purified blood through said
31 cuff into said venous outflow catheter which
32 is located in the right atrium and the blood is
33 directly deposited into the right atrium.

OPINION

Rejection of Claim 17

ISSUES

The Appellants argue the rejection of claim 17 separately from the rejections of the remaining claims. In view of the Examiner's findings and conclusions, and the Appellants' contentions, the following issues are raised in with regard to the rejection of claim 17:

- *First*, is Park analogous art? (*Compare* Br. 18 and 24 with Ans. 10).
- *Second*, would one of ordinary skill in the art familiar with the combined teachings of Squitieri, Park and Twardowski have had reason to modify the hemodialysis and vascular system taught by Squitieri to include a single lumen venous outflow catheter comprising a depositing end configured for insertion through a vein into the right atrium of the heart? (*Compare* Br. 15 and 24 with Ans. 7-8).
- *Third*, would one of ordinary skill in the art familiar with the combined teachings of Squitieri, Park and Twardowski have had reason to modify the method of using Squitieri's system to include a step of depositing blood directly into the right atrium of the heart? (*Id.*)
- *Fourth*, would the subject matter of claim 17 have been prima facie obvious even assuming for purposes of this appeal only that the combined teachings of Squitieri, Park and Twardowski would have provided one of ordinary skill in the art no reason to modify

Squitieri's system to include certain features of the Appellants' preferred embodiment related to the recited cylindrical cuff which were pointed out in the Appeal Brief but not recited in claim 17? (*Compare* Br. 15-16, 18-19 and 24 *with* Ans. 9).

- *Fifth*, does the probative value of the evidence supporting the Examiner's conclusion that the subject matter of claim 17 would have been obvious outweigh the probative value of the Appellants' objective evidence of nonobviousness? (*Compare* Br. 25-27 *with* Ans. 12).

FINDINGS OF FACT

The record supports the following additional findings of fact ("FF") by a preponderance of the evidence.

1. We adopt the Examiner's finding that:

Squitieri discloses an arteriovenous shunt system comprising an arterial graft 53 with a lead end 62 anastomosed to an artery and [a] terminal end connected to needle access site 80, which acts as a connector that corresponds to applicant's cuff. . . . The access site 80, corresponding to applicant's cuff, directs passage of blood from the arterial catheter to the venous catheter, and is in communication with the terminal end of the arterial graft and the inlet end of the venous catheter (see FIGS 6-9, column 5, lines 19-60).

(Ans. 4).

2. Squitieri discloses that a preferred size for a graft serving the purpose of graft 53 would be approximately 7 mm in diameter and

1 transitioning downward to an open end portion of approximately 4 mm in
2 diameter. (*See* Squitieri, col. 3, l. 67 – col. 4, l. 2).

3 3. We adopt the Examiner’s finding that Squitieri’s arteriovenous
4 shunt system “further comprises a venous outflow catheter 65 with an
5 outflow end that is capable of being inserted through a vein.” (Ans. 4).

6 4. Squitieri describes tube 65 as including a plurality of
7 perforations 66 at the outflow end of the tube and that the outlet end is
8 positioned in the venous system 67. (Squitieri, col. 5, ll. 45-48). Figure 7 of
9 Squitieri depicts the outflow end of the tube 65 positioned upstream of the
10 heart near the position of the right atrium.

11 5. Squitieri teaches that positioning the outflow end of the tube 65
12 in the venous system 67 avoids problems associated with anastomosing the
13 outflow end to vein. (Squitieri, col. 2, ll. 27-32). Squitieri does not
14 mention, much less criticize or disparage, placement of the outflow end in
15 the right atrium of the heart.

16 6. Squitieri recognizes that excessive turbulence and shear forces
17 in the vascular system are undesirable. (*See* Squitieri, col. 3, ll. 5-8).

18 7. We adopt the Examiner’s finding that “Twardowski discloses
19 an apparatus and method for hemodialysis in which a venous catheter
20 comprises a distal end 138a disposed within the right atrium, delivering
21 treated blood to the right atrium in order to provide a long-term indwelling
22 catheter.” (Ans. 7, citing Twardowski, col. 6, ll. 15-48; col. 11, ll. 15-35;
23 and fig. 9).

24 8. Twardowski’s indwelling catheter is a double-lumen catheter.
25 (Twardowski, col. 6, ll. 15-16).

1 9. Twardowski teaches that “such catheters are preferably
2 proportioned to be implanted in a major vein of the patient, with the distal
3 tip of the catheter being positioned in the right atrium of the heart. This
4 provides a high and turbulent blood flow to the catheter distal tip, as well as
5 a bigger chamber, which minimizes the chances for the catheter distal tip to
6 press against the wall thereof.” (Twardowski, col. 3, ll. 45-51).

7 Twardowski also recognizes that reducing pressure and abrasion against
8 blood vessel walls has the advantage of reduction in clotting and tissue
9 irritation, thereby providing a catheter which is capable of long-term
10 indwelling in the arteriovenous system of a patient. (Twardowski, col. 3, ll.
11 17-21).

12 10. Twardowski teaches that the dimensions of the catheter may be
13 chosen to match the vein in which the catheter is to be implanted.
14 (Twardowski, col. 4, ll. 47-49).

15 11. Parks discloses an enteral feeding device including a ferrule.
16 (Parks, col. 3, ll. 67-68).

17 12. Figure 13 of Parks discloses a cuff or ferrule 212 in which the
18 transition 220 between a larger inner diameter at one end and a narrower
19 inner diameter at the other end is longer and at a shallower angle than other
20 examples depicted in Parks. The upper end of the ferrule 212 as depicted in
21 Figure 13 includes conical walls 218, 220 which would enable a tubular
22 conduit to be inserted (*see* Parks, col. 7, ll. 50-54) in such a manner as to
23 provide a degree of continuity between the inner diameter of the tubular
24 conduit and the diameter of the wall 220 near the inserted end of the conduit.

25 13. The Appellants in their Specification do not disclose any detail
26 of the interior configuration of the preferred cuff 13 which connects their

1 preferred arteriovenous graft *11* to their preferred venous outflow catheter
2 *12*. (*See, e.g.*, Spec. 9, para. 0026 and fig. 1).

3 14. The Appellants present an unexecuted declaration to which the
4 results of two studies are attached. Each involved “HeRO” vascular access
5 devices, which the Appellants’ unexecuted declaration identifies as
6 hemodialysis arteriovenous shunts “identical to the applicants claimed
7 invention.”

8 15. One study, reported by a Dr. H. Katzman, reached the
9 conclusion that the bacteremia rate associated with the “HeRO” device
10 surpassed bacteremia rates from IJ tunneled dialysis (TDC) and graft
11 literature. The study also concluded that the patency rate associated with the
12 “HeRO” device surpassed the patency rate from the TDC literature and was
13 comparable to the patency rate from graft literature. (Exhibit 1 to
14 declaration). The other study, reported by a Dr. Chris Stout and others,
15 reported successful placement of the “HeRO” device in fifty of fifty-two
16 patients to undergo placement attempts. (Exhibit 2 to declaration).

17 16. Neither study compares the subject matter of claim 17 to a
18 system of the type described by Squitieri.

19 17. The only arguable evidence which the Appellants appear to
20 provide to show that the results reported in the two studies were unexpected
21 is a bare statement to that effect in the unexecuted declaration and arguments
22 in the Appeal Brief.

23 18. Trerotola discloses a body implantable device in the form of a
24 stent-graft extending between a brachial artery and an auxiliary vein.
25 (Trerotola, col. 3, ll. 57-60 and col. 6, ll. 21-22). Trerotola also teaches the

1 use of polyurethane as a biostable flexible material. (Trerotola, col. 2, ll. 29-
2 33).

3
4 PRINCIPLES OF LAW

5 In determining whether the subject matter of a claim would have been
6 obvious, an examiner must undertake the factual inquiries listed in *Graham*
7 *v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). In order to justify rejecting a
8 claim as unpatentable, the examiner must articulate some “reasoning with
9 some rational underpinning to support the legal conclusion of obviousness.”
10 *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir 2006). This reasoning must show
11 that “there was an apparent reason to combine the known elements in the
12 fashion claimed.” *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007).
13 The apparent reason need not appear in, or be suggested by, one or more of
14 the references on which the examiner relies. Instead, the examiner may
15 employ common sense not inconsistent with the ordinary level of knowledge
16 and skill in the art when analyzing the evidence. *Perfect Web Techs. v.*
17 *InfoUSA, Inc.*, 587 F.3d 1324, 1328-29 (Fed. Cir. 2009).

18 In order to reject a claim under section 103(a), an examiner must
19 establish at least a “prima facie” case that the claimed subject matter would
20 have been obvious. Once the examiner produces prima facie evidence that
21 the claimed subject matter would have been obvious, the applicant may
22 present additional evidence tending to rebut the examiner’s conclusion that
23 the claimed subject matter would have been obvious. If the applicant
24 presents additional evidence to rebut the examiner’s conclusion, the
25 examiner must consider all of the evidence anew. If the evidence presented
26 by the examiner and any evidence presented by the applicant, considered

1 anew, demonstrate that the claimed subject matter would have been obvious
2 to one of ordinary skill in the art, the claim is properly rejected under
3 § 103(a). *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984).

4
5 ANALYSIS

6 Parks is analogous art. The established precedent of our reviewing
7 court sets up a two-fold test for determining whether art is analogous:
8 “First, we decide if the reference is within the field of the inventor’s
9 endeavor. If it is not, we proceed to determine whether the reference is
10 reasonably pertinent to the particular problem with which the inventor was
11 involved.” *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986). Claim 17
12 expressly recites that the diameters of arterial graft and the venous outflow
13 catheter differ. Therefore, one problem with which the Appellants were
14 involved was the problem of connecting two tubes of different diameter.
15 Parks is within the medical field, broadly speaking, and addresses this
16 problem by means of Parks’ ferrule or connector 70. Since Parks is
17 reasonably pertinent to a particular problem with which the inventor was
18 involved, Parks is analogous art.

19 One of ordinary skill in the art would have had reason to modify the
20 hemodialysis and vascular system taught by Squitieri to include a single
21 lumen venous outflow catheter comprising a depositing end configured for
22 insertion through a vein into the right atrium of the heart. Twardowski
23 teaches providing a long-term indwelling catheter by disposing a distal end
24 138a of the catheter within the right atrium and delivering treated blood to
25 the right atrium. (FF 7). As the Examiner correctly concludes, it would
26 have been obvious “to advance the catheter disclosed by the cited prior art

1 deeper into the patient's vasculature to the right atrium, as disclosed by
2 Twardowski, in order to provide a long-term indwelling catheter without
3 major drawbacks." (Ans. 7-8). More specifically, Squitieri recognizes that
4 excessive turbulence and shear forces in the vascular system is undesirable.
5 (FF 6). Twardowski teaches that extending a catheter conducting a
6 hemodialysis outflow to the right atrium of the heart provides a bigger
7 chamber in which to deposit turbulent, high shear outflow, "which
8 minimizes the chances for the catheter distal tip to press against the wall
9 thereof." (FF 9). One of ordinary skill in the art would have recognized that
10 placing the outflow of Squitieri's single-lumen catheter in the right atrium
11 would reduce the pressure and abrasion on the wall tissue near the outflow,
12 thereby providing a long-term indwelling catheter. (*See id.*)

13 As the previous paragraph indicates, the teachings of Squitieri are not
14 inconsistent with those of Twardowski. Squitieri teaches that positioning the
15 outflow end of the venous outflow catheter 65 in the venous system 67
16 avoids problems associated with anastomosing the outflow end to the vein.
17 (FF 5). This advantage would not be undermined by extending the venous
18 outflow catheter into the heart as taught by Twardowski. Although
19 Twardowski describes a double-lumen catheter (FF 8) and Squitieri's tube
20 65 appears to have only one lumen, this structural difference would not have
21 dissuaded one of ordinary skill in the art from applying Twardowski's
22 teachings concerning the advantages of depositing the outflow into the right
23 atrium of the heart rather than into a vein. As the Examiner points out, the
24 claimed subject matter may have been obvious from the teachings of the
25 prior art even if the preferred embodiments described in the prior art cannot
26 be physically combined. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981).

1 Claim 17 does not recite a cuff made of biocompatible material, a cuff
2 which covers the venous outflow catheter only or a cuff which connects the
3 outflow catheter to the arterial graft by surgical anastomosis. Assuming for
4 purposes of this appeal only that the combined teachings of Squitieri, Park
5 and Twardowski would have provided one of ordinary skill in the art no
6 reason to modify Squitieri's system to include a cuff having these features,
7 this assumption would not foreclose a conclusion that the subject matter of
8 claim 17 would have been obvious.

9 The Appellants appear to contend that the combined teachings of
10 Squitieri, Parks and Twardowski would have provided one of ordinary skill
11 in the art no reason to connect an arterial graft and a venous outflow catheter
12 of the types described by Squitieri (and as expanded in view of the teachings
13 of Twardowski) by means of a cuff disposed about ends of the graft and
14 catheter which "provides a secure fit for said arterial graft first diameter and
15 said venous outflow catheter second diameter." Even assuming, as the
16 Appellants argue, that particular embodiments of Parks' cuff or ferrule have
17 ridged inner surfaces and would act as foreign bodies within the lumen of
18 the arterial graft and the venous outflow catheter, leading to obstruction of
19 the flow of blood and thrombosis (*see* Br. 18-19), these concerns would not
20 have discouraged one of ordinary skill in the art from the combination
21 proposed by the Examiner.

22 For example, Figure 13 of Parks discloses cuff or ferrule 212 in which
23 the transition 220 between a larger inner diameter at one end and a narrower
24 inner diameter at the other end is longer and at a shallower angle than other
25 examples depicted in Parks. The upper end of the ferrule 212 as depicted in
26 Figure 13 includes conical walls 218, 220 which would enable a tubular

1 conduit to be inserted in such a manner as to provide a degree of continuity
2 between the inner diameter of the tubular conduit and the diameter of the
3 wall 220 near the inserted end of the conduit. (FF 12). Assuming, as the
4 Appellants appear to assert, that one of ordinary skill in the art would
5 recognize that a ridged inner surface would disrupt laminar blood flow,
6 Figure 13 of Parks would have provided guidance to one of ordinary skill in
7 the art as to how to reduce the disruption of laminar blood flow through the
8 cuff or ferrule. The Appellants' assertion that the ridged inner surfaces of
9 some embodiments of Parks' ferrules would have discouraged those of
10 ordinary skill in the art from combining elements from Squitieri, Parks and
11 Twardowski in the fashion claimed in claim 17 is not persuasive.

12 The Appellant's assertion is particularly unpersuasive in view of their
13 failure to disclose in their Specification any details of the interior of their
14 preferred cuff 13. (See FF 13). The absence of such disclosure implies that
15 the Appellants believed as of their filing date that one of ordinary skill in the
16 art seeking to practice the subject matter of claim 17 had sufficient skill to
17 design or procure a cuff capable of connecting an arteriovenous graft to a
18 venous outflow catheter of different diameter without disrupting laminar
19 blood between the two. Since it was within the level of ordinary skill to
20 design or procure such as cuff, a need to do so would not have discouraged
21 one of ordinary skill in the art from modifying Squitieri's system in the
22 fashion claimed in claim 17.

23 For these reasons, we conclude that the subject matter of claim 17
24 would have been prima facie obvious from the combined teachings of
25 Squitieri, Parks and Twardowski. Since the Appellants have submitted
26 evidence in rebuttal of obviousness, we now turn to consider this evidence.

1 When such evidence is presented it is our duty to consider the evidence
2 anew. *See, e.g., In re Eli Lilly & Co.*, 902 F.2d 943, 945 (Fed. Cir. 1990).
3 We also are mindful that objective evidence of nonobviousness in any given
4 case may be entitled to more or less weight depending on its nature and its
5 relationship with the merits of the invention. *Stratoflex Inc. v. Aeroquip*
6 *Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983).

7 The probative value of the Appellants' objective evidence is low. As
8 the Examiner points out, the Appellants provide no evidence of an actual
9 long felt need in the art and rely on nothing more than unsupported argument
10 as evidence of commercial success. (*See* Ans. 12; *see also* Br. 26 and 27).
11 The Appellants' evidence of unexpected result is less insubstantial. (*See* FF
12 15).

13 Nevertheless, two factors to be considered in determining the weight
14 to be given evidence of unexpected results is the degree to which the
15 evidence compares results of the claimed subject matter against those of the
16 closest prior art and the degree to which the evidence shows that the results
17 are unexpected. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1370-71
18 (Fed. Cir. 2007). The Appellants' evidence fails to compare the claimed
19 subject matter against the closest prior art, Squitieri. Neither do the
20 Appellants provide evidence or reasoning to support their assertion that the
21 bacteremial and patency results identified in the evidence would have been
22 unexpected. (FF 16 and 17). Having considered the evidence presented by
23 the Appellants and weighed all of the evidence anew, the weight of the
24 evidence supports the Examiner's legal conclusion that the subject matter of
25 claim 17 would have been obvious.

CONCLUSIONS

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Park is analogous art.

One of ordinary skill in the art familiar with the combined teachings of Squitieri, Park and Twardowski would have had reason to modify the hemodialysis and vascular system taught by Squitieri to include a single lumen venous outflow catheter comprising a depositing end configured for insertion through a vein into the right atrium of the heart.

One of ordinary skill in the art familiar with the combined teachings of Squitieri, Park and Twardowski would have had reason to modify the method of using Squitieri's system to include a step of depositing blood directly into the right atrium of the heart.

The subject matter of claim 17 would have been prima facie obvious even assuming for purposes of this appeal only that the combined teachings of Squitieri, Park and Twardowski would have provided one of ordinary skill in the art no reason to modify Squitieri's system to include certain features of the Appellants' preferred embodiment related to the recited cylindrical cuff which were pointed out in the Appeal Brief but not recited in claim 17.

The probative value of the evidence supporting the Examiner's conclusion that the subject matter of claim 17 would have been obvious outweighs the probative value of the Appellants' objective evidence of nonobviousness.

We sustain the rejection of claim 17 under § 103(a) as being unpatentable over Squitieri, Parks and Twardowski.

1 *Remaining Claim Rejections*

2 Claims 1 and 13 are independent. Claim 1 recites an arteriovenous
3 shunt including a single lumen venous outflow catheter. Claim 13 recites a
4 system including an arteriovenous shunt with a single lumen venous outflow
5 catheter. In both claim 1 and claim 13, the single lumen venous outflow
6 catheter comprises an intake end and a depositing end. The depositing end
7 is configured for insertion through a vein into the right atrium of the heart.

8 Without the teachings of Twardowski, the Examiner has identified
9 nothing in the combined teachings of Squitieri and Parks which might have
10 suggested to one of ordinary skill in the art to extend an outlet end of an
11 outlet tube such as Squitieri's tube 65 to reach into the right atrium of the
12 heart. (*See, e.g.*, Ans. 5 and 8-9). Neither has the Examiner articulated any
13 reason why one of ordinary skill in the art familiar with the teachings of
14 Squitieri and Parks might have modified Squitieri's system so that an outlet
15 end of an outlet tube extended into the right atrium. The Examiner's finding
16 that Squitieri teaches the outlet tube 65 might be of various sizes does not
17 imply in and of itself a reason why one of ordinary skill in the art might have
18 extended the tube to reach into the right atrium. We do not sustain the
19 Examiner's rejection of claims 1-5, 7-10, 12-14, 17 and 18 under § 103(a) as
20 being unpatentable over Squitieri and Parks.

21 Neither does the Examiner articulate reasoning adequate to explain
22 how the teachings of Trerotola remedies the deficiencies in the teachings of
23 Squitieri for purposes of the rejection of claim 10 or the deficiencies in the
24 combined teachings of Squitieri and Parks for purposes of the rejections of
25 claims 6, 11, 15, 16, 19 and 20. We do not sustain the rejections of claims 6,
26 11, 15, 16, 19 and 20 under § 103(a) as being unpatentable over Squitieri,

1 Parks and Trerotola or the rejection of claim 10 under § 103(a) as being
2 unpatentable over Squitieri and Trerotola.

3
4 DECISION

5 We AFFIRM the Examiner's decision rejecting claim 17.

6 We REVERSE the Examiner's decision rejecting claims 1-16 and 18-
7 20.

8 No time period for taking any subsequent action in connection with
9 this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R.
10 § 1.136(a)(1)(iv) (2007).

11
12 AFFIRMED-IN-PART

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15 Klh

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